DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV - 5 1996

Mr. Byron J. Johnson
Vice President and General Counsel
Nutrilite
5600 Beach Boulevard
P.O. Box 5940
Buena Park, California 90622-5940

Dear Mr. Johnson:

This is in response to your letter of September 11, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for your product NUTRILITE® Echinacea with Astragalus Dietary Supplement:

> Echinacea increases the body's white cell rate of neutralizing potentially harmful microbes (germs).

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat or mitigate disease, in that it claims to "increase the body's white cell rate of neutralizing potentially harmful microbes (germs)." This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 28

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

NUTRILITE
A Division of Amway Corporation

5600 Beach Boulevard • PO Box 5940 • Buena Park CA 90622-5940 • 714 562-3200

September 11, 1996

Elizabeth A. Yetley, Director
Office of Special Nutritionals, HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Re: **NUTRILITE® Echinacea with Astragalus Dietary Supplement**

Dear Dr. Yetley:

Pursuant to Section 6(c) of the Dietary Supplement Health and Education Act of 1994, this is to inform you that Nutrilite intends to make the following claims on the label of the above referenced product:

"Echinacea increases the body's white cell rate of neutralizing potentially harmful microbes (germs)."

Very truly yours,

Byron J. Johnson
Vice President and General Counsel

48708